

## **REMARKS**

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1-3, 5, 7, 11, 13, 15, 17, 19, 20, 22, 23, 25, 26, 28-32, 34-41, 101, and 104-107 are pending in this application. Claims 1-3, 40 and 41 are amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

The amendment to claims 1, 2, 40, and 41 is to clarify the transfer means of the claimed invention. Support for the amendment to claim 3 can be found, for example, on page 11, lines 21-25. No new matter is added.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicant is entitled.

### **II. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME**

#### **Definiteness**

Claims 3, 5, 7, 11, 13, 15, 17, 19, 20, 22, 23, 25, 26, and 39 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Office Action contended that the specification does not describe a “harvesting means” as separate from a “removal means.” The rejection is respectfully traversed.

Applicant draws attention to instant claim 3, which recites a harvesting means “for harvesting cells from the chamber by dislodging cells that are attached to the surface of the chamber.” Applicant thereby asserts that the harvesting means is separate from the removal means, which removes “a sampling of cells, comprising undifferentiated cells, from the chamber

into a storage container,” as recited in claim 3. Thus, claim 3, as well as claims 5, 7, 11, 13, 15, 17, 19, 20, 22, 23, 25, 26, and 39 which are dependent therefrom, is definite.

Accordingly, reconsideration and withdrawal of the Section 112, second paragraph rejection are requested.

**Written Description**

Claims 3, 5, 7, 11, 13, 15, 17, 19, 20, 22, 23, 25, 26 and 39 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The rejection is respectfully traversed.

The Office Action alleged that the specification does not provide a structure for the harvesting means recited in claims 3 and 15, such that the structure of the harvesting means would be different from the structure of the removal means. In response, Applicant reiterates that instant claim 3 recites that the harvesting means is for “harvesting cells from the chamber by dislodging cells that are attached to the surface of the chamber.” Such a harvesting means is supported in the specification, in particular on page 11, lines 21-25. Thus, the harvesting means is clearly distinguished from the removal means and complies with the written description requirements.

The Office Action also contended that claim 3 recites “transfer means for transferring a column agent to the chamber,” “mixing means for mixing the cell population and agent within the chamber,” and “cell population comprises haematopoietic cells,” which are all embodiments required for claim 1. The Office Action alleged that it is unclear how the recitation of these embodiments further limits the scope of claim 1. In response, Applicant notes that instant claim 3 recites “wherein the means for introducing an agent into the chamber [of claim 1] is a transfer means for transferring a volume of agent to the chamber, and/or a transfer means for transferring a calculated volume of agent to the chamber.” Further, instant claim 3 does not recite “wherein the cell population comprises haematopoietic cells” or “mixing means for mixing the cell population and agent within the chamber.” Consequently, claims 1 and 3 do not relate to the same embodiments, and claim 3 properly depends from claim 1.

Accordingly, reconsideration and withdrawal of the Section 112, first paragraph rejection are requested.

### **III. THE REJECTIONS UNDER 35 U.S.C. § 102 ARE OVERCOME**

Claims 1-3, 7, 17, 19, 20, 22, 23, 25, 26, 28, 29-32, and 34-41 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Gilford (U.S. Patent No. 4,058,367). Claims 1-3, 7, 17, 19, 20, 22, 23, 25, 26, 28-32, and 34-41 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Tomioka *et al.* (U.S. Patent No. 4,983,359). These rejections are traversed and will be addressed collectively.

Applicant points out that, in order for a Section 102 rejection to stand, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Further, the prior art must contain an enabling disclosure. *See Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). With this in consideration, Applicant asserts that Gilford and Tomioka *et al.* do not anticipate the claimed invention, as neither reference contains all of the elements of the claimed invention.

The instant claims relate to a device comprising a device comprising a chamber, means for introducing into the chamber a cell population including committed cells or haematopoietic cells, means for introducing into the chamber an agent, incubation means for incubating the committed cells in the presence of the agent, and mixing means for mixing the agent and the cell population in the chamber, wherein said agent is selected from the group consisting of (a) an antibody that binds to MHC antigens, (b) erythropoietin, and (c) GM-CSF. Applicant submits that the agent introduced into the chamber should be given full patentable weight, as the agent is an element of the claimed device. There is no recitation of intended use of the agent in the instant claims.

Gilford relates to an apparatus for processing fluids for ascertaining physical and/or chemical properties of the fluids, but does not teach or even suggest an apparatus that comprises an agent selected from the group consisting of an antibody that binds to MHC antigens, erythropoietin, and GM-CSF.

Tomioka *et al.* relates to an apparatus for measuring lymphocyte subclasses comprising a staining means for mixing and reacting a tagged monoclonal antibody with a blood sample, a sensing station, a laser light source, sensors, and a data processing means. Tomioka *et al.* does not teach or even suggest an agent selected from the group consisting of an antibody that binds to MHC antigens, erythropoietin, and GM-CSF. Applicants note that the antibodies of Tomioka *et*

*al.* bind to specific antigens associated with lymphocyte subclasses (see Tomioka *et al.*, col. 4, ll. 40-44); Tomioka *et al.* is silent as to antibodies of MHC antigens.

Hence, neither Gilford nor Tomioka *et al.* teach or suggest every element of the claimed invention. Accordingly, reconsideration and withdrawal of the Section 102 rejections are requested.

#### **IV. THE REJECTIONS UNDER 35 U.S.C. § 103 ARE OVERCOME**

Claims 1-3, 5, 7, 17, 19, 20, 22, 23, 25, 26, 28, 29-32, and 34-41 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Gilford in view of North (U.S. Patent Publication No. 2001/0052763). Claims 1-3, 7, 11, 13, 17, 19, 20, 22, 23, 25, 26, 28-32, and 34-41 were rejected under 35 U.S.C. § 103(a) as allegedly being upatentable over Tomioka *et al.* in view of Johnson (U.S. Patent No. 4,563,907). These rejections are traversed and will be addressed collectively.

Establishing a *prima facie* case of obviousness requires that the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP 2143. The Examiner is also respectfully reminded that in order to ground an obviousness rejection, there must be some teaching which would have provided the necessary incentive or motivation for modifying the reference's teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). As stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Office Action does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Furthermore, the Supreme Court has recently reaffirmed the factors set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18: "[T]he scope and content of the prior art are determined; differences between the prior art and the claims at issue are...ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give

light to the circumstances surrounding the origin of the subject matter sought to be patented.”  
*KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_\_ (2007).

With this in mind, Applicants assert that neither the combination of Gilford and North nor the combination of Tomioka *et al.* and Johnson render the instant claims unpatentable, as neither combination teaches or suggests every element of the claimed invention.

As described above, the device of the instant claims comprise an agent selected from the group consisting of an antibody that binds to MHC antigens, erythropoietin, and GM-CSF. Gilford does not teach or suggest a device that comprises such an agent, and North does not remedy this deficiency. Similarly, Tomioka *et al.* does not teach or suggest an apparatus that comprises an antibody **that binds to MHC antigens**, erythropoietin, or GM-CSF; Johnson, too, does not remedy this deficiency. Thus, neither combination of references teaches or suggests every element of the instant claims.

Applicants additionally assert that Tomioka *et al.* teaches away from the instant invention. Tomioka relates to antibodies that bind specifically to lymphocyte subclasses (see Tomioka *et al.*, col. 4, ll. 40-44). In contrast, the present invention relates to an antibody that binds to MHC antigens, which are common to most undifferentiated cells and differentiated cells (see present specification, page 29, lines 20-22). Therefore, Tomioka *et al.* teaches away from the present invention, because Tomioka *et al.* relates to antigens that are specific lymphocyte subclasses, rather than common to most cells.

Thus, neither the combination of Gilford and North nor the combination of Tomioka *et al.* and Johnson render the instant claims unpatentable. Accordingly, reconsideration and withdrawal of the Section 103 rejections are requested.

**REQUEST FOR INTERVIEW**

If any issue remains as an impediment to allowance, an interview with the Examiner and SPE are respectfully requested and the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

**CONCLUSION**

In view of the remarks and amendments herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,  
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